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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/296,534 04/22/99 HALLOWITZ

R BIOTI-7

023599 HM12/0403  
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EXAMINER

ZEMAN, R

ART UNIT

PAPER NUMBER

1645

DATE MAILED:

04/03/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

**Advisory Action**Application No.  
**09/296,534**Applicant(s)  
**Hallowitz et al.**Examiner  
**Robert A. Zeman**Group Art Unit  
**1645****THE PERIOD FOR RESPONSE:** [check only a) or b)]

- a) ☐ expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☐ expires either three months from the mailing date of the final rejection, or on the mailing date of this Advisory Action, whichever is later. In no event, however, will the statutory period for the response expire later than six months from the date of the final rejection.

Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a), the proposed response and the appropriate fee. The date on which the response, the petition, and the fee have been filed is the date of the response and also the date for the purposes of determining the period of extension and the corresponding amount of the fee. Any extension fee pursuant to 37 CFR 1.17 will be calculated from the date of the originally set shortened statutory period for response or as set forth in b) above.

- ☒ Appellant's Brief is due two months from the date of the Notice of Appeal filed on Dec 18, 2000 (or within any period for response set forth above, whichever is later). See 37 CFR 1.191(d) and 37 CFR 1.192(a).

Applicant's response to the final rejection, filed on Mar 19, 2001 has been considered with the following effect, but is NOT deemed to place the application in condition for allowance:

☐ The proposed amendment(s):

- ☐ will be entered upon filing of a Notice of Appeal and an Appeal Brief.
- ☐ will not be entered because:
- ☐ they raise new issues that would require further consideration and/or search. (See note below).
- ☐ they raise the issue of new matter. (See note below).
- ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.
- ☐ they present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

- ☐ Applicant's response has overcome the following rejection(s): \_\_\_\_\_
- \_\_\_\_\_

- ☐ Newly proposed or amended claims \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment cancelling the non-allowable claims.

- ☒ The affidavit, exhibit or request for reconsideration has been considered but does NOT place the application in condition for allowance because:

see attached

- ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

- ☒ For purposes of Appeal, the status of the claims is as follows (see attached written explanation, if any):

Claims allowed: \_\_\_\_\_

Claims objected to: \_\_\_\_\_

Claims rejected: 1-16

- ☐ The proposed drawing correction filed on \_\_\_\_\_ ☐ has ☐ has not been approved by the Examiner.
- ☐ Note the attached Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☐ Other

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### **ADVISORY ACTION**

Applicant's response filed on 3-19-2001 is acknowledged. No claims have been amended. Claims 1-16 are currently pending.

#### ***Priority***

The objection to the specification with regard to the priority statement is maintained for reasons of record. Application No. 09/139,663 is still improperly referred to as Application No. 09/139,633 throughout the specification.

#### ***Oath/Declaration***

The objection based on the oath or declaration being defective is maintained for reasons of record. The oath fails to identify priority documents by application number and filing date therein.

#### ***Claim Rejections Maintained***

##### ***35 USC § 103***

The rejection of claims 1-13 and 15-16 under 35 U.S.C. 103(a) as being unpatentable over Chun et al (Nature Vol. 387, pages 183-188 May 1997) in view of Chun et al.( Nature Medicine Vol. 1 Number 12, pages 1284-1290. December 1995) and Essex et al. (U.S. Patent 4,725,669) and the rejection of claim 13 under 35 U.S.C. 103(a) as being unpatentable over Chun et al

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(Nature Vol. 387, pages 183-188 May 1997) in view of Chun et al. (Nature Medicine Vol. 1 Number 12, pages 1284-1290. December 1995) and Essex et al. (U.S. Patent 4,725,669) and Chun et al (Journal of Experimental Medicine. Vol. 188 Number 1, July 6, 1998 pp 83-91) are maintained for reasons of record.

Applicant argues:

1. No evidence has been provided by the Patent Office that gp120 is only produced when a cell is productively infected with HIV-1
2. gp120 expression can be dissociated from the production of infectious virus as is present when protease inhibitors are administered.
3. Fessel et al. shows that indexes of HIV infection cannot be interchangeably used to diagnose productive infection, and hence, underlying latent viral load.

Applicant's arguments have been fully considered and been deemed to be non-persuasive.

With regard to Applicant's arguments regarding when gp120 is produced are not supported by factual evidence and therefore are not persuasive.

With regard to Applicant's arguments regarding protease inhibitors, these elements are not limitations of the pending claims.

With regard to Applicant's arguments based on Fessel et al., said reference was published after the filing date and hence is not indicative of what was known in the art at the time of the invention. Additionally, in as far as Fessel et al. **could** indicate an unexpected result, no such evidence has been submitted.

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Chun et al. discloses the same method steps as those of the instant invention, using a well known HIV-1 antigen. Essex provides a disclosure of the claimed antigen and indicates it is very useful for detecting HIV-1 infection. These disclosures indicate that the antigens are essentially equivalent and interchangeable. Absent of evidence to the contrary, one of skill in the art would have had a reasonable expectation of success to produce the claimed method using gp120.

*Conclusion*

**No claim is allowed.**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (703) 308-7991. The examiner can be reached between the hours of 7:30 am and 4:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, Donna Wortman, Primary Examiner can be reached at (703) 308-1032 or the examiner's supervisor, Lynette Smith, can be reached at (703)308-3909.

  
DONNA WORTMAN  
PRIMARY EXAMINER

Robert A. Zeman

March 29, 2001